



DEPARTMENT OF HEALTH & HUMAN SERVICES

94604d

Public Health Service  
Food and Drug Administration  
Los Angeles District

19701 Fairchild  
Irvine, California 92612-2506  
Telephone (949) 608-2900

## WARNING LETTER

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

March 29, 2004

W/L 33-04

Mr. George L. Tong, President  
Gemini Food Corporation  
251 Benton Court  
Walnut, CA 91789

Dear Mr. Tong:

On December 24, 2003, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 251 Benton Court, Walnut, CA 91789. The inspection was conducted to determine your firm's compliance with seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 342(a)(4)). Accordingly, the jellyfish and fried fish that you imported from [REDACTED] and that FDA inspected on the above date is adulterated in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The HACCP deviations were as follows:

If you obtain fish or fishery products from a country that does not have a qualifying memorandum of understanding (MOU) or similar agreement with the FDA, you must have and implement written verification procedures for ensuring that the fish or fishery products were processed in accordance with the requirements of 21 CFR Part 123.

1. Your written verification procedures must list, at a minimum, product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm could not provide product specifications for jelly fish and fried fish imported from [REDACTED]

2. In addition, you must implement an affirmative step that ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for jellyfish manufactured by [REDACTED] in [REDACTED] and fried fish manufactured by [REDACTED] in [REDACTED]

This inspection was a follow-up to a previous inspection conducted March 27, 2003, to verify that you had taken corrective actions to implement written verification procedures for your importation of fish sauce from [REDACTED]. You were informed during that inspection that your importation of fish and fishery products is subject to the verification requirements in 21 CFR 123.12.

We may take action without further notice if you do not promptly correct these violations. For example, we may seize your products and/or enjoin your firm from operating. In addition, FDA may detain your imported seafood products without examination. Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations and assure that such violations will not recur. You may wish to include in your response copies of records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act, the seafood HACCP regulation, and the Current Good Manufacturing Practice regulation. You also have a responsibility to use procedure to prevent further violations of the Act and all applicable regulations.

Your written reply should be directed to:

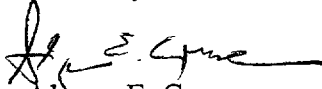
U.S. Food & Drug Administration  
Attn: John L. Stevens  
Director, Import Operations Branch  
Los Angeles District  
222 West 6<sup>th</sup> Street, Suite 700  
San Pedro, CA 90731

Letter to Mr. George L. Tong, President, Gemini Food Corp.

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If you have questions regarding the implementation of the Seafood HACCP Regulation, you may contact Ruth P. Dixon, Compliance Officer, at (310) 971-2299.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is stylized with a large initial "A" and a long horizontal stroke extending to the right.

Alonza E. Cruse

District Director